

Environmental Protection Agency

§ 158.1

Subparts P–T [Reserved]

158.1500–158.1900 [Reserved]

Subpart U—Biochemical Pesticides

- 158.2000 Biochemical pesticides definition and applicability.
- 158.2010 Biochemical pesticides data requirements.
- 158.2030 Biochemical pesticides product chemistry data requirements table.
- 158.2040 Biochemical pesticides residue data requirements table.
- 158.2050 Biochemical pesticides human health assessment data requirements table.
- 158.2060 Biochemical pesticides nontarget organisms and environmental fate data requirements table.
- 158.2070 Biochemical pesticides product performance data requirements.
- 158.2080 Experimental use permit data requirements—biochemical pesticides.
- 158.2081 Experimental use permit biochemical pesticides product chemistry data requirements table.
- 158.2082 Experimental use permit biochemical pesticides residue data requirements table.
- 158.2083 Experimental use permit biochemical pesticides human health assessment data requirements table.
- 158.2084 Experimental use permit biochemical pesticides nontarget organisms and environmental fate data requirements table.

Subpart V—Microbial Pesticides

- 158.2100 Microbial pesticides definition and applicability.
- 158.2110 Microbial pesticides data requirements.
- 158.2120 Microbial pesticides product analysis data requirements table.
- 158.2130 Microbial pesticides residue data requirements table.
- 158.2140 Microbial pesticides toxicology data requirements table.
- 158.2150 Microbial pesticides nontarget organisms and environmental fate data requirements table.
- 158.2160 Microbial pesticides product performance data requirements.
- 158.2170 Experimental use permit data requirements—microbial pesticides.
- 158.2171 Experimental use permit microbial pesticides product analysis data requirements table.
- 158.2172 Experimental use permit microbial pesticides residue data requirements table.
- 158.2173 Experimental use permit microbial pesticides toxicology data requirements table.

158.2174 Experimental use permit microbial pesticides nontarget organisms and environmental fate data requirements table.

Subpart W—Antimicrobial Pesticides [Reserved]

158.2200 [Reserved]

Subpart X–Z [Reserved]

158.2300–158.2500 [Reserved]

AUTHORITY: 7 U.S.C. 136–136y; 21 U.S.C. 346a.

SOURCE: 72 FR 60957, Oct. 26, 2007, unless otherwise noted.

Subpart A—General Provisions

§ 158.1 Purpose and scope.

(a) *Purpose.* The purpose of this part is to specify the kinds of data and information EPA requires in order to make regulatory judgments under FIFRA secs. 3, 4, and 5 about the risks and benefits of pesticide products. Further, this part specifies the data and information needed to determine the safety of pesticide chemical residues under FFDCA sec. 408.

(b) *Scope.* (1) This part describes the minimum data and information EPA typically requires to support an application for pesticide registration or amendment; support the reregistration of a pesticide product; support the maintenance of a pesticide registration by means of the data call-in process, e.g., as used in the registration review program; or establish or maintain a tolerance or exemption from the requirements of a tolerance for a pesticide chemical residue.

(2) This part establishes general policies and procedures associated with the submission of data in support of a pesticide regulatory action.

(3) This part does not include study protocols, methodology, or standards for conducting or reporting test results; nor does this part describe how the Agency uses or evaluates the data and information in its risk assessment and risk management decisions, or the regulatory determinations that may be based upon the data.

(c) *Scope of individual subparts.* (1) *Conventional pesticides.* Subparts A, B, C, D, F, G, K, L, N, and O apply to conventional pesticides.

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(2) *Biochemical pesticides*. Subparts A, B and U apply to biochemical pesticides.

(3) *Microbial pesticides*. Subparts A, B and V apply to microbial pesticides.

(4) *Antimicrobial pesticides*. [Reserved]

§ 158.3 Definitions.

All terms defined in sec. 2 of the Federal Insecticide, Fungicide, and Rodenticide Act apply to this part and are used with the meaning given in the Act. Applicable terms from the Federal Food, Drug, and Cosmetic Act also apply to this part. Individual subparts may contain definitions that pertain solely to that subpart. The following additional terms apply to this part:

Applicant means any person or entity, including for the purposes of this part a registrant, who submits, or is required to submit, to the Agency any application, petition, or submission intended to persuade EPA to grant, modify, or leave unmodified a registration or other approval required as a condition of sale or distribution of a pesticide. Such submissions may include, but are not limited to, the following:

(1) An application for registration or amended registration of a pesticide product under FIFRA sec. 3 or 24.

(2) A submission of data required in conjunction with reregistration of a currently registered product under FIFRA sec. 4.

(3) An application for an experimental use permit under FIFRA sec. 5.

(4) A submission of data in response to a notice issued by EPA under FIFRA sec. 3(c)(2)(B).

(5) A petition to establish or modify a tolerance or an exemption from the requirement of a tolerance for a pesticide chemical residue under FFDCA sec. 408.

Registration includes a new registration, amended registration and reregistration, unless stated otherwise.

§ 158.5 Applicability.

(a) The requirements of this part apply to the following submissions:

(1) An application for new or amended registration under FIFRA sec. 3 or 24.

(2) An application for experimental use permit under FIFRA sec. 5.

(3) A submission of data or information to support the continuation of a registration under FIFRA sec. 3, 4, or 24.

(4) A petition to establish, modify or revoke a tolerance or exemption from a tolerance under FFDCA sec. 408.

(b) The information specified in this part must be furnished with each submission described in paragraph (a) of this section if it has not been submitted previously, or if any previous submission is not accurate or complete.

§ 158.30 Flexibility.

(a) FIFRA provides EPA flexibility to require, or not require, data and information for the purposes of making regulatory judgments for pesticide products. EPA has the authority to establish or modify data needs for individual pesticide chemicals. The actual data required may be modified on an individual basis to fully characterize the use and properties, characteristics, or effects of specific pesticide products under review. The Agency encourages each applicant to consult with EPA to discuss the data requirements particular to its product prior to and during the registration process.

(b) The Agency cautions applicants that the data routinely required in this part may not be sufficient to permit EPA to evaluate the potential of the product to cause unreasonable adverse effects to man or the environment. EPA may require the submission of additional data or information beyond that specified in this part if such data or information are needed to appropriately evaluate a pesticide product.

(c) This part will be updated as needed to reflect evolving program needs and advances in science.

§ 158.32 Format of data submissions.

(a) *General*. (1) All data submitted under this part must be formatted in accordance with this section.

(2) The requirements of this section do not apply to administrative materials accompanying a data submission, including forms, labeling, and correspondence.